JUL 26 2011

SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K_____

GENERAL INFORMATION

Applicant:

CorMatrix Cardiovascular, Inc.
155-A Moffett Park Dr., Suite 240
Sunnyvale, CA 94089-1330
U.S.A.
Phone: 408-734-2628
FAX: 408-734-2629

Contact Person:

Heather Lake
Regulatory Consultant
Experien Group, LLC
155-A Moffett Park Dr., Suite 210
Sunnyvale, CA 94089
U.S.A.
Phone: 408-400-0856
FAX: 408-400-0865

Date Prepared: April 26, 2011

DEVICE INFORMATION

Classification:

21 CFR§870.3470, Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluroethylene

Product Code:

DXZ

Trade Name:

CorMatrix® ECM® for Carotid Repair

Generic/Common Name:

Patch, Pledget and Intracardiac

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICES

- CorMatrix® ECM® for Cardiac Tissue Repair (K063349)
- Cook® Biotech Surgisis® Peripheral Vascular Patch (K001785)
- Bio-Vascular/Synovis® Vascu-Guard® Peripheral Vascular Patch (K983602)
- Carbomedics Vascutek Thin Wall Carotid Patch (K963611)

INTENDED USE

The CorMatrix® ECM® for Carotid Repair is intended for use as a patch material for vascular reconstruction and repair of the carotid artery, including patch closure following carotid endarterectomy and suture line buttressing.

PRODUCT DESCRIPTION

The CorMatrix ECM for Carotid Repair is an extracellular matrix (ECM) scaffold derived from porcine small intestinal submucosa (SIS). SIS is developed from a select layer of tissue that is recovered from porcine small intestine. During processing, the inner and outer muscle layers of the material are removed, leaving an intact submucosa with a portion of the tunica propria layer attached to the outer surface. Following processing, the remaining acellular ECM material is cut to specific shapes and sizes, lyophilized, and terminally sterilized using Ethylene Oxide gas.

The CorMatrix ECM for Carotid Repair is derived from the same SIS-ECM material as CorMatrix's two commercially available products, the CorMatrix ECM for Pericardial Closure and the CorMatrix ECM for Cardiac Tissue Repair. The CorMatrix ECM for Carotid Repair will be supplied as a multilaminate, lyophilized, sterilized sheet of SIS-ECM. The CorMatrix ECM will be provided in four sizes: 1x10cm, 1x15cm, 2x10cm and 2x15cm sheets.

SUBSTANTIAL EQUIVALENCE

The indications for use for the CorMatrix ECM for Carotid Repair are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the CorMatrix ECM for Carotid Repair is substantially equivalent to the predicate devices.

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510(k) SUMMARY (CONT.)

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and animal testing was conducted on the CorMatrix ECM for Carotid Repair to support a determination of substantial equivalence to the predicate devices.

Nonclinical Testing Summary:

The nonclinical testing assessed the following aspects of the device:

- Suture retention strength
- Probe burst strength
- Tensile strength
- Biocompatibility
- Sterilization validation
- Packaging and shelf-life

Animal testing examined the safety and performance, as well as burst pressures of repaired vessels at various time points. The collective results of the nonclinical testing demonstrate that the CorMatrix ECM for Carotid Repair meets the established specifications necessary for consistent performance for its intended use. The collective nonclinical testing demonstrates that the CorMatrix ECM for Carotid Repair does not raise new questions of safety or efficacy for carotid artery repair.

SUMMARY

The CorMatrix ECM for Carotid Repair is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CorMatrix Cardiovascular, Inc.
c/o Kit Cariquitan
155 Moffett Park Dr., Suite 210
Sunnyvale, CA 94089

JUL 26 2011

Re: K111187
Trade/Device Name: CorMatrix® ECM® for Carotid Repair
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: April 26, 2011
Received: April 27, 2011

Dear Mr. Cariquitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111187

Device Name: CorMatrix® ECM® for Carotid Repair

Indications For Use:

The CorMatrix® ECM® for Carotid Repair is intended for use as a patch material for vascular reconstruction and repair of the carotid artery, including patch closure following carotid endarterectomy and suture line buttressing.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111187